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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/646,835
Filing Date: January 11, 2001
Appellant(s): MULTHOFF, GABRIELE

Robert Goetz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 1, 2007 appealing from the Office action mailed April 4, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 61-77 and 83-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a method of activating NK cells using either a HSP protein of SEQ ID No: 1, a C-terminal fragment comprising amino acids 384-641 of SEQ ID No: 1, and therefore the written description is not commensurate in scope to the claims that read on a method of activiating NK cells using a polypeptide having 70% or greater homology to amino acid 384-641 of SEQ ID No: 1, as claimed. The following *written description* rejection is set forth herein.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Appellant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims recite a "a polypeptide having 70% or greater homology to amino acid 384-641 of SEQ ID No: 1" as part of the invention. However, there does not appear to

be an adequate written description in the specification as-filed of the essential structural features that are representative of the genus of sequences that are 70% or greater in homology to amino acids 384-641 of SEQ ID No: 1 as claimed. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the appellant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Appellant does not appear to have reduced to practice any sequence that is 70% or greater in homology to amino acid 384-641 of SEQ ID No: 1. With the exception of SEQ ID NO:1 or fragments comprising amino acids 384-641 of SEQ ID No: 1, the skilled artisan cannot envision the detailed structure of the encompassed polypeptide variants or those that have at least 70% homology to amino acids 384-641 of SEQ ID No: 1 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Neither has Appellant provided a sufficient written description of any structure that may be correlated with any specific function or identification of a core structure responsible for any specific function. The genus of sequences encompassed is extensive and the

artisan would not be able to recognize that Appellant was in possession of the invention as now claimed.

Consequently, Appellant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id. While it is noted that the instant claims are drawn to methods, the claims nevertheless require an adequate written description of the "polypeptides having 70% or greater homology with amino acids 384-641 of SEQ ID No: 1" employed in the methods.

Appellant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Appellant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Therefore only a method of activating NK cells using either a HSP protein of SEQ ID No: 1, a C-terminal fragment comprising amino acids 384-641 of SEQ ID No: 1 meets the written description provision of 35 USC 112, first paragraph.

(10) Response to Argument

1. Eli Lilly is not Controlling

At page 6 of Brief, appellant contends that the case of *Regents of University of California v. Eli Lilly*, is not controlling. Specifically, appellant contends that the issue at *Eli Lilly* was that the specification nor the claims disclosed the sequence of human insulin. Appellant argue that the instant case differs because the sequence of Hsp70 was provided in the specification, claims, and also well known in the prior art and was therefore not attempting to define a genus by function alone. Appellant further argues that the cited case of *Noelle v. Lederman* is not applicable because the specification provides specific sequences and the sequence of Hsp70 was known in the art.

At page 7 of the Brief, appellant indicated that sequences which are 70% or greater in homology have been reduced to practice in the specification and further point to examples of sequence in the art which fall within the scope of the claimed limitations of which could be used in the claimed method. Appellant further contend that both the specification and the art provide those of skill in the art with a vast source of the genus of Hsp70 which are encompassed by the claimed method. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

In deciding *The Reagents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997), the Federal Circuit held that a generic statement that defines a genus of nucleic acids *by only their functional activity* does not provide an adequate written description of the genus. By analogy, a generic statement that defines a genus of polypeptides having 70% or greater homology to amino acids 384-641 of SEQ ID No:

1 by only their common ability to induce an immune response by NK cells, wherein the response increases cytolytic activity of the NK cells or stimulates NK cell proliferation does not serve to adequately describe the genus as whole. The Court indicated that while Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

"[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, as in that, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written description requirement the genus of structurally variable polypeptides that is at least 70% homologous to amino acids 384-641 wherein the polypeptide is capable of

inducing an immune response by NK cells as specifically claimed. Although appellants have pointed to several species of HSPs that may fall within the genus of at least 70% homologous to amino acids 384-641 of SEQ ID No: 1, as indicated by the Courts, the claimed genus is unpredictable with regards to those species that have not been specifically enumerated. Specifically, the claims encompass polypeptide variants that are at least 70% identical to amino acids 384-641 of SEQ ID No: 1. Neither the specification nor the art of record have specifically indicated which portions of the polypeptide within amino acids of 384-641 of SEQ ID No: 1 are required for the claimed function. Moreover, the claims encompass variants of polypeptides comprising amino acids 384-641 of SEQ ID No: 1 and the specification has not provided any guidance on what sequences or amino acids substitutions could be made or modified without affecting the polypeptides ability to induce an immune response by NK cells as claimed. Again, a description of what a material does, rather than of what it is, does not suffice to describe the claimed invention. Although it is true that the instant application has provided a sequence for Hsp70, what it has not done is provide a core structure correlative to the claimed functionality of inducing NK immune response which the members of the genus must comprise.

At page 8 of the Brief, Appellant further argues, that even if one of skill in the art did not want to rely on the teachings provided in the art, the specification as filed provided sufficient guidance on how to make and test appropriate derivatives of the exemplified Hsp70 protein and fragments thereof (example 1 of the specification). Appellant's arguments have been carefully considered but are not deemed persuasive

to overcome the rejection of record.

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed. Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). Moreover, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. In the instant case, a method of making and screening for polypeptides that are at least 70% homologous to amino acids 384-641 of SEQ ID No: 1 does not provide specific information regarding the specific structure or function or a know correlation between structure and function. It essentially provides for a starting point for those of skill in the art to experiment and look for those structural variants. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Appellant has not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Appellant has not described distinguishing identifying characteristics sufficient to show possession of the claimed invention at the time the application was filed.

2. Application of the Written Description Guidelines compels allowance of the claims.

At page 9 of the Brief, Appellant to argue by referring to Example 14 of "Synopsis of Application of Written Description Guidelines". Appellant indicates that the facts of the instant case are analogous to those presented in example 14 because members of the genus claimed do not significantly vary because all sequence must be at least 70% homologous to amino acids 384-641 of SEQ ID No: 1 and further must possess the activity of inducing an immune response by NK cells. Appellant also indicates that "SEQ ID No: 1 is a representative species for the genus since all polypeptides must have at least 70% homology to this sequence." Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Example 14, as, discusses sequence variants that are at least 95% or great in identity to a reference sequence. The sequences encompassed by the limitation of 95% or greater was deemed not to differ or vary significantly also it was coupled with a known function of catalyzing a reaction of A to B. In the instant case, the sequences encompassed by the limitation of at least 70% identity is much broader in scope and include sequences that have yet to be disclosed and further not specifically identified by either the appellant and those of skill in the art. Moreover, the function claimed in the instant case, is not a specific function of the protein, but rather a characteristic of the peptide or any peptide, because any peptide when administered in vitro or in vivo would have such a function and therefore applies generally to any peptide fragment. As indicated above, neither the specification nor the prior art teaches which portions within

amino acids 384-641 of SEQ ID No: 1 is critical for the induction of an immune response by NK cells. As such, given the limited disclosure regarding the genus of polypeptides claimed, the Appellant's disclosure is deficient in written description.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christopher Yaen

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August 31, 2007

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